IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S, LEO LABORATORIES LIMITED, and LEO PHARMA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs LEO Pharma A/S ("LEO Pharma"), LEO Laboratories Limited ("LEO Labs"), and LEO Pharma, Inc. ("LEO, Inc.") (collectively, "LEO") by their attorneys, for their complaint against Actavis Laboratories UT, Inc. ("Actavis"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(a), (b), (c), (e) and (g). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 208807 and 209086 (collectively, "the Actavis ANDAs"), filed by and for the benefit of Actavis with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of LEO Pharma's PICATO® innovative pharmaceutical products, which are gels containing ingenol mebutate as the active pharmaceutical ingredient at dosage strengths of 0.015% and 0.05%.

THE PARTIES

2. Plaintiff LEO Pharma is a company organized and existing under the laws of Denmark with its headquarters at Industriparken 55, DK-2750 Ballerup, Denmark. LEO Pharma is a research-based company dedicated to developing innovative drugs to help patients with dermatologic conditions.

3. Plaintiff LEO Labs is a company organized and existing under the laws of Ireland with its headquarters at 285 Cashel Road, Dublin 12, Ireland. LEO Labs is a wholly owned subsidiary of LEO Pharma.

4. Plaintiff LEO, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1 Sylvan Way, Parsippany, NJ 07054. LEO, Inc. is a wholly owned subsidiary of LEO Pharma.

5. On information and belief, Defendant Actavis is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 577 S. Chipeta Way, Salt Lake City, Utah 84108.

6. On information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

7. On information and belief, Actavis has participated and collaborated in the research and development, and the preparation and filing, of the Actavis ANDAs, continues to participate and collaborate in seeking FDA approval of the Actavis ANDAs, intends to participate and collaborate in the commercial manufacture, marketing offer for sale, and sale of Actavis's ANDA Products throughout the United States, including this judicial district, and stands to benefit from the approval of the Actavis ANDAs.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement arising under the patent laws of the United States of America, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 9,820,959 ("the '959 Patent"), U.S. Patent No. 9,833,428 ("the '428 Patent"), and U.S. Patent No. 9,833,429 ("the '429 Patent") (collectively, "the Patents-in-Suit").

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Actavis because Actavis is a corporation organized under the laws of the State of Delaware, and therefore, is subject to the laws and protections of the State of Delaware.

11. This Court also has personal jurisdiction over Actavis because it has continuous and systemic contacts with Delaware. Further, Actavis has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to LEO, which manufactures PICATO® for sale and use throughout the United States, including in this judicial district. In addition, on information and belief, if the Actavis ANDAs were to receive approval, Actavis would market and sell generic versions of PICATO® in Delaware.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

LEO'S APPROVED PICATO® DRUG PRODUCTS AND PATENTS

13. LEO Pharma is the holder of New Drug Application ("NDA") No. 202833 for ingenol mebutate gel, 0.015% and 0.05%, which was approved by FDA on January 23, 2012. LEO Pharma and LEO, Inc. market the innovative approved drug products under the trade name PICATO®.

14. The active pharmaceutical ingredient in PICATO® is ingenol mebutate, also referred to as ingenol-3-angelate.

15. PICATO® is the first approved pharmaceutical product to contain the compound ingenol mebutate. In recognition of this, the FDA awarded PICATO® New Chemical Entity ("NCE") exclusivity, which expired January 23, 2017, pursuant to 21 C.F.R. § 314.108.

16. LEO Pharma's PICATO® products are approved for the topical treatment of actinic keratosis. A true and correct copy of the prescribing information for LEO Pharma's PICATO® products approved in NDA No. 202833 is attached as Exhibit A.

17. FDA has awarded PICATO® gel, 0.015%, additional exclusivity based on studies provided in a Supplemental NDA, which expires November 19, 2018.

18. The PICATO® products and their use are covered by claims of the Patents-in-Suit.

19. The Patents-in-Suit are listed/will be listed in FDA's Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 202833.

20. The '959 Patent, entitled "Therapeutic Compositions," was duly and legally issued by the United States Patent and Trademark Office on November 21, 2017. The Orange Book presently shows that the '959 Patent's term ends on December 18, 2026. A true, correct, and complete copy of the '959 Patent is attached hereto as Exhibit B.

21. The '428 Patent, entitled "Therapeutic Compositions," was duly and legally issued by the United States Patent and Trademark Office on December 5, 2017. The Orange Book will show that the '428 Patent's term ends on December 18, 2026. A true, correct, and complete copy of the '428 Patent is attached hereto as Exhibit C.

22. The '429 Patent, entitled "Therapeutic Compositions," was duly and legally issued by the United States Patent and Trademark Office on December 5, 2017. The Orange Book will show that the '429 Patent's term ends on December 18, 2026. A true, correct, and complete copy of the '429 Patent is attached hereto as Exhibit D.

ANDA NO. 208807 AND ANDA NO. 209086

23. Actavis has submitted or caused to be submitted ANDA No. 208807 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture,

use, or sale of Ingenol Mebutate Gel, 0.015%, as a purported generic version of PICATO®, prior to the expiration of the Patents-in-Suit. Actavis's generic Ingenol Mebutate Gel, 0.015%, is a formulation that comprises ingenol mebutate, also known as ingenol-3-angelate, as its active pharmaceutical ingredient.

24. Actavis has also submitted or caused to be submitted ANDA No. 209086 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Ingenol Mebutate Gel, 0.05%, as a purported generic version of PICATO®, prior to the expiration of the Patents-in-Suit. Actavis's generic Ingenol Mebutate Gel, 0.05% (together with Actavis's Ingenol Mebutate Gel, 0.015%, the "ANDA Products"), is a formulation that comprises ingenol mebutate, also known as ingenol-3-angelate, as its active pharmaceutical ingredient.

25. LEO received a letter from Actavis, dated March 25, 2016, representing that Actavis had submitted to FDA ANDA No. 208807 with a paragraph IV certification for certain other U.S. patents (the "Related LEO Patents") covering PICATO® (the "0.015% Notice Letter"). The purpose of the ANDA is to obtain FDA approval to engage in the commercial manufacture and sale of a generic version of LEO Pharma's PICATO® product before the expiration of the Related LEO Patents.

26. LEO also received a letter from Actavis, dated March 25, 2016, representing that Actavis had submitted to FDA ANDA No. 209086 with a paragraph IV certification for the Related LEO Patents covering PICATO® (the "0.05% Notice Letter"). The purpose of the ANDA is to obtain FDA approval to engage in the commercial manufacture and sale of a generic version of LEO Pharma's PICATO® product before the expiration of the Related LEO Patents.

27. The 0.05% Notice Letter and the 0.015% Notice Letter state that the Paragraph IV certifications Actavis made in the ANDAs allege that the Related LEO Patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Actavis ANDAs.

28. Another action is pending in this judicial district between LEO and Actavis. Its caption is *LEO Pharma A/S et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 16-333 (the "Related Action"). In the Related Action, LEO alleges that Actavis's ANDA Products infringe on the Related LEO Patents and other U.S. patents owned by LEO, and Actavis contends that such patents are unenforceable, invalid, and/or that its ANDA Products would not infringe on such patents.

29. The Patents-in-Suit are continuations of patents among the Related LEO Patents; share subject matter, inventors, and specifications with the Related LEO Patents; and contain patent claims that are related to the claims in the Related LEO Patents and directed to similar subject matter.

30. On information and belief, Actavis will assert that the Patents-in-Suit are unenforceable, invalid, and/or that its ANDA Products would not infringe on the Patents-in-Suit for the same or similar reasons it asserts in the Related Action.

31. On information and belief, Actavis intends to and will send LEO a paragraph IV certification for the Patents-in-Suit.

32. Hence, Actavis's purpose in submitting the Actavis ANDAs is to gain approval from the FDA to manufacture and market the ANDA Products before the expiration of the Patents-in-Suit.

33. Actavis produced copies of its ANDAs in the Related Litigation, which LEO has reviewed under the terms of a confidentiality and protective order in that case.

34. Actavis has assisted with and participated in the preparation and submission of the Actavis ANDAs, has provided material support to the preparation and submission of the Actavis ANDAs, and intends to support the further prosecution of the Actavis ANDAs.

35. On information and belief, if FDA approves the Actavis ANDAs, Actavis will manufacture, offer for sale, or sell Actavis's ANDA Products within the United States, including within Delaware, or will import Actavis's ANDA Products into the United States, including Delaware.

36. On information and belief, if FDA approves the Actavis ANDAs, Actavis will actively induce or contribute to the manufacture, use, offer for sale, or sale of Actavis's ANDA Products.

37. Actavis's ANDA Products are manufactured in the state of Utah.

38. On information and belief, Actavis seeks to use, offer, or sell Actavis's ANDA Products prior to the expiration of the Process Patents-in-Suit.

39. This action was brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days after the date of LEO's receipt of paragraph IV notice letters related to Actavis's ANDAs and the Patents-in-Suit.

COUNT 1
(Infringement Of The '959 Patent)

40. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

41. Actavis has submitted or caused the submission of the Actavis ANDAs to FDA, and continues to seek FDA approval of the Actavis ANDAs.

42. Actavis has infringed the ’959 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Actavis ANDAs and seeking FDA approval of the Actavis ANDAs prior to the expiration of the ’959 Patent.

43. The ’959 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein the formulation is a topical formulation and comprises specified amounts of ingenol-3-angelate, and said ingenol-3-angelate permeates the skin at a specified rate.

44. Actavis’s ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the formulation is a topical formulation and comprises the specified amounts of ingenol-3-angelate, and said ingenol-3-angelate permeates the skin at the specified rate.

45. Actavis’s commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis’s ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of the ’959 Patent. Upon information and belief, upon FDA approval of the Actavis ANDAs, Actavis will market and distribute Actavis’s ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Actavis ANDAs, Actavis will make, use, offer to sell, or sell Actavis’s ANDA Products within the United States, or will import Actavis’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’959 Patent.

46. LEO will be irreparably harmed if Actavis is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the ’959 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and

Actavis, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2
(Declaratory Judgment Of Infringement Of The '959 Patent)

47. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

48. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. The '959 Patent includes claims that recite a pharmaceutical formulation comprising ingenol angelate, wherein the formulation is a topical formulation and comprises specified amounts of ingenol-3-angelate, and said ingenol-3-angelate permeates the skin at a specified rate.

50. Actavis's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, wherein the formulation is a topical formulation and comprises the specified amounts of ingenol-3-angelate, and said ingenol-3-angelate permeates the skin at the specified rate.

51. On information and belief, if the Actavis ANDAs are approved, Actavis's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Actavis and its affiliates. Actavis will therefore infringe one or more claims of the '959 Patent under 35 U.S.C. § 271(a).

52. On information and belief, Actavis's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Actavis's ANDA Products complained of herein, will begin immediately after the FDA approves the Actavis ANDAs. Any such conduct before the '959 Patent expires will infringe, contribute to the infringement of and/or induce the

infringement of one or more claims of the ’959 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

53. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Actavis concerning liability for the infringement of the ’959 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

54. LEO will be substantially and irreparably harmed by Actavis’s infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

55. This case is exceptional, and LEO is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 3
(Infringement Of The ’428 Patent)

56. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

57. Actavis has submitted or caused the submission of the Actavis ANDAs to FDA, and continues to seek FDA approval of the Actavis ANDAs.

58. Actavis has infringed the ’428 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Actavis ANDAs and seeking FDA approval of the Actavis ANDAs prior to the expiration of the ’428 Patent.

59. The ’428 Patent includes claims that recite a formulation comprising ingenol angelate, of which specified amounts are ingenol-3-angelate; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical, gel formation and comprises ingenol-3-angelate in a specified amount by weight.

60. Actavis's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, of which a specified amount is ingenol-3-angelate; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical, gel formation and comprises ingenol-3-angelate in the specified amount by weight.

61. Actavis's commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's ANDA Products would directly infringe, and/or would actively induce and/or contribute to infringement of the '428 Patent. Upon information and belief, upon FDA approval of the Actavis ANDAs, Actavis will market and distribute Actavis's ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Actavis ANDAs, Actavis will make, use, offer to sell, or sell Actavis's ANDA Products within the United States, or will import Actavis's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '428 Patent.

62. LEO will be irreparably harmed if Actavis is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the '428 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Actavis, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 4
(Declaratory Judgment Of Infringement Of The '428 Patent)

63. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

64. LEO's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. The ’428 Patent includes claims that recite a formulation comprising ingenol angelate, of specified amounts are ingenol-3-angelate; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical, gel formation and comprises ingenol-3-angelate in a specified amount by weight.

66. Actavis’s ANDA Products contain a formulation comprising ingenol angelate, of which a specified amount is ingenol-3-angelate; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical, gel formation and comprises ingenol-3-angelate in the specified amount by weight.

67. On information and belief, if the Actavis ANDAs are approved, Actavis’s ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Actavis and its affiliates. Actavis will therefore infringe one or more claims of the ’428 Patent under 35 U.S.C. § 271(a).

68. On information and belief, Actavis’s infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Actavis’s ANDA Products complained of herein, will begin immediately after the FDA approves the Actavis ANDAs. Any such conduct before the ’428 Patent expires will infringe, contribute to the infringement of and/or induce the infringement of one or more claims of the ’428 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

69. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Actavis concerning liability for the infringement of the ’428 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

70. LEO will be substantially and irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

71. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 5
(Infringement Of The '429 Patent)

72. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

73. Actavis has submitted or caused the submission of the Actavis ANDAs to FDA, and continues to seek FDA approval of the Actavis ANDAs.

74. Actavis has infringed the '429 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Actavis ANDAs and seeking FDA approval of the Actavis ANDAs prior to the expiration of the '429 Patent.

75. The '429 Patent includes claims that recite a formulation comprising ingenol angelate, of which specified amounts are ingenol-3-angelate; a penetration enhancer; a gelling agent; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical formulation and comprises ingenol-3-angelate in a specified amount by weight.

76. Actavis's ANDA Products contain a pharmaceutical formulation comprising ingenol angelate, of which a specified amount is ingenol-3-angelate; a penetration enhancer; a gelling agent; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical formulation and comprises ingenol-3-angelate in the specified amount by weight.

77. Actavis's commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's ANDA Products would directly infringe, and/or would actively

induce and/or contribute to infringement of the ’429 Patent. Upon information and belief, upon FDA approval of the Actavis ANDAs, Actavis will market and distribute Actavis’s ANDA Products to third parties including resellers, pharmacies, hospitals and other clinics. Accordingly, unless enjoined by this Court, upon FDA approval of the Actavis ANDAs, Actavis will make, use, offer to sell, or sell Actavis’s ANDA Products within the United States, or will import Actavis’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’429 Patent.

78. LEO will be irreparably harmed if Actavis is not enjoined from infringing and from actively inducing and/or contributing to the infringement of the ’429 Patent. LEO does not have an adequate remedy at law, and considering the balance of hardships between LEO and Actavis, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 6
(Declaratory Judgment Of Infringement Of The ’429 Patent)

79. LEO incorporates by reference each of the preceding paragraphs as if fully set forth herein.

80. LEO’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

81. The ’429 Patent includes claims that recite a formulation comprising ingenol angelate, of which specified amounts are ingenol-3-angelate; a penetration enhancer; a gelling agent; an acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical formulation and comprises ingenol-3-angelate in a specified amount by weight.

82. Actavis’s ANDA Products contain a formulation comprising ingenol angelate, of which a specified amount is ingenol-3-angelate; a penetration enhancer; a gelling agent; an

acidifying agent; and a pharmaceutically acceptable solvent, wherein the formulation is a topical formulation and comprises ingenol-3-angelate in the specified amount by weight.

83. On information and belief, if the Actavis ANDAs are approved, Actavis's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Actavis and its affiliates. Actavis will therefore infringe one or more claims of the '429 Patent under 35 U.S.C. § 271(a).

84. On information and belief, Actavis's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Actavis's ANDA Products complained of herein will begin immediately after the FDA approves the Actavis ANDAs. Any such conduct before the '429 Patent expires will infringe, contribute to the infringement of and/or induce the infringement of one or more claims of the '429 Patent under one or more of 35 U.S.C. §§ 271 (a), (b) and (c).

85. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between LEO and Actavis concerning liability for the infringement of the '429 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

86. LEO will be substantially and irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. LEO has no adequate remedy at law.

87. This case is exceptional, and LEO is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, LEO seeks the following relief:

A. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Actavis's submission to the FDA of ANDA Nos. 208807 and 209086 to obtain approval for the commercial

manufacture, use, offer for sale, or sale in, or importation into, the United States of the Actavis's ANDA Products before the expiration of the '959 Patent was an act of infringement of one or more claims of the '959 Patent;

B. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Actavis's submission to the FDA of ANDA Nos. 208807 and 209086 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Actavis's ANDA Products before the expiration of the '428 Patent was an act of infringement of one or more claims of the '428 Patent;

C. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A) Actavis's submission to the FDA of ANDA Nos. 208807 and 209086 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Actavis's ANDA Products before the expiration of the '429 Patent was an act of infringement of one or more claims of the '429 Patent;

D. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Actavis's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Actavis's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '959 Patent;

E. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Actavis's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Actavis's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '428 Patent;

F. A declaratory judgment that under one or more of 35 U.S.C. § 271(a), (b) and (c), Actavis's commercial manufacture, use, offer for sale, or sale in, or importation into, the United

States of the Actavis's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '429 Patent;

G. The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Actavis, its affiliates and subsidiaries, and all persons and entities acting in concert with Actavis from commercially manufacturing, using, offering for sale, or selling Actavis's ANDA Products within the United States, or importing Actavis's ANDA Products into the United States, until the expiration of the Patents-in-Suit;

H. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA Nos. 208807 and 209086 shall be no earlier than the last expiration of any of the Patents-in-Suit, or any later expiration of exclusivity for any of the Patents-in-Suit, including any extensions or regulatory exclusivities;

I. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Actavis engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Products, or any product that infringes the '959 Patent, or induces or contributes to such conduct, prior to the expiration of the '959 Patent;

J. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Actavis engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Products, or any product that infringes the '428 Patent, or induces or contributes to such conduct, prior to the expiration of the '428 Patent;

K. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Actavis engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Products, or any product that infringes the '429 Patent, or induces or contributes to such conduct, prior to the expiration of the '429 Patent;

L. An award to LEO of its costs and expenses in this action; and

M. Such further and other relief as this Court determines to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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